

Surelease[®] Ethylcellulose Dispersion Type B NF, is optimally plasticized for modified release and taste masking applications. Using ethylcellulose as the rate controlling polymer, Surelease delivers dependable and reproducible extended release profiles that are consistent from laboratory to pilot and production scale processes. General use, preparation and clean up guidelines are outlined in this information sheet.

USE GUIDELINES

- Surelease is a fully formulated and optimally plasticized system supplied at 25% w/w solids content. For best results, the product should be diluted to 15% w/w solids.
- Due to the high pH of Surelease, the addition of Lake color to the dispersion is not recommended. Color can be added to the top-coat if desired.
- A clear (or colored) Opadry[®], complete film coating system/Opadry[®] II, high performance film coating system topcoat is recommended at 1-3% weight gains to prevent blocking.
- Need of curing to achieve stable drug release profile during storage must be evaluated on a case by case basis. Curing of the film may not be necessary when processed under recommended conditions.
- Release profiles are controlled by Surelease film thickness and drug release can be modelled using the Ficks laws of diffusion.

PREPARATION GUIDELINES

Materials

- Surelease dispersion
- Water, maximum temperature 30°C (deionized or distilled)

Equipment

- Variable speed mixer and propeller stirrer
- Mixing vessel large enough to contain desired quantity of dispersion

Mixing Procedure

- Gently agitate the container of Surelease to ensure complete dispersion of solids.

Coating Formulation

- Surelease dispersion (25% solids) 60% w/w
- Water (distilled or deionized) 40% w/w
- Add the water to the Surelease dispersion and mix with a low shear mixer for approximately 15 minutes.
- It is recommended to continue gentle agitation throughout the coating process to prevent sedimentation.

CLEAN UP GUIDELINES

- For best results, the coating over-spray should be cleaned off equipment shortly after the end of the coating run. If the product is allowed to dry the residual film can be difficult to remove.
- Fluid bed equipment can be cleaned by spraying a cleaning solution (such as sodium bicarbonate) or mild soap and water into the chamber and bowl. The cleaning solution can also be brushed on the equipment surfaces. Continue application until the film is soft and removable.
- (15 to 30 minutes). The cleaning solution will not dissolve the film coating, but allows it to release from the metal so it can be washed away with water.
- Coating pans can also be cleaned with the solution. Fill the reservoir and allow the pan to rotate through the solution for 30 minutes. When the film becomes soft it can be rinsed off with water.
- Spray equipment (guns and hoses) should be disassembled and cleaned with the appropriate solution. When cleaning spray guns, it is important to make sure the passages are free of residual coating material that can block the orifice and restrict flow. A thin soft brush or swab can be passed through the tip of the gun to insure all the coating material is removed. Avoid using hard substances because these can damage the gun parts.
- All equipment should be rinsed with deionized water after cleaning.

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